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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,250	08/20/2003	Muktar A. Mahajan	57953/1151	7913

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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,250	MAHAJAN ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006 and 16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit I*.

DETAILED ACTION

This action is in response to the amendment, filed 12/4/2006, in which claims 2 and 8-91 were canceled, and claims 1 and 3 were amended. Receipt is also acknowledged of a supplemental amendment, filed 1/16/2007, in which the declaration under 37 CFR 1.131 was provided. Currently, claims 1 and 3-7 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Election/Restrictions

Applicant elected Group I (claims 1-7, SEQ ID NOS: 1, 3 and 4) with traverse in the reply filed 3/10/2006. Currently, claims 1 and 3-7 are under consideration as they read on SEQ ID NOS: 1, 3 and 4.

It is noted that claims 1 and 3-7 read on non-elected inventions (i.e., the sequences of SEQ ID NOS: 5 and 6). It is suggested that any reply to the final rejection include cancellation of nonelected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

Applicants' claim for the benefit of a Provisional Application 60/405,752 application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/405,752 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application does not provide a written description of the polynucleotide identified in claim 2 as Sequence ID NO: 4, a nucleotide sequence in which the region 5' to the start codon of the NIF-1 encoding nucleic acid (instant SEQ ID NO: 1) is truncated wherein the truncated region is not required for expression of the translated protein. Accordingly, claims 1 and 3-7 are not entitled to the benefit of the prior application.

The effective filing date of claims 1 and 3-7 is the filing date of the instant application, 8/20/2003.

***Response to* Arguments - Claim Objections**

The objection of claim 2 has been withdrawn in view of Applicant's amendment to the claims in the reply filed 12/4/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection, necessitated by the amendment of claim 1 to include some of the limitations of claim 2 in a manner which is inconsistent with the previous interpretation of claim 2 (i.e., that claim 2 was interpreted as an isolated nucleic acid molecule having a sequence comprising SEQ ID NO: 1, or sequences that hybridize to SEQ ID NO: 1).

The claims are drawn to a genus of nucleic acid molecules selected from the group consisting of (i) a nucleic acid molecule having a nucleotide sequence of SEQ ID NO: 1, (ii) a nucleic acid molecule having a nucleotide sequence of SEQ ID NO: 4, (iii) a nucleic acid molecule encoding an amino acid sequence having SEQ ID NO: 3, and (iv) a nucleic acid molecule having a nucleotide sequence that is at least 85% similar to the nucleotide sequence of SEQ ID NOS: 1 or 4 by basic BLAST using default parameters analysis. The recitation of "a nucleotide sequence" reads on any nucleotide sequence of two or more nucleotides. Thus, the claims encompass a broad genus of nucleic acid molecules that share "a sequence" with SEQ ID NO: 1 or 4. Further, the claims encompass a genus of nucleic acid molecules that have "a sequence" (i.e., 2 or more nucleotides) that have at least 85% similarity with the nucleotide sequence of SEQ ID NOS: 1 or 4. The percent similarity comparison does not require the

nucleic acid molecules to be compared over the full-length of SEQ ID NOS: 1 or 4. Accordingly, the rejected claims thus comprise an enormous genus of nucleic acid molecules that are required to encode a protein or polypeptide that modulates transcriptional activation in a cell with or without collaboration with a nuclear hormone receptor transcriptional co-activator.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes the nucleic acid sequence of SEQ ID NO: 1, which is a nucleic acid sequence of 4439 nucleotides that encodes the NIF-1 polypeptide of SEQ ID NO: 2 (e.g., paragraph [0039]). The specification describes the nucleic acid sequence of SEQ ID NO: 3 as an amino acid sequence of 1342 amino acids, which represents the functional domains of NIF-1 (e.g., paragraph [0039]). SEQ ID NO: 2 is 1357 amino acids in length, and SEQ ID NO: 3 is 100% identical to amino acids 16-1357 of SEQ ID NO: 2. The specification describes six zinc finger domains, a leucine zipper-like motif and an LxxLL motif in SEQ ID NOS: 2 and 3 (e.g., paragraphs [0039] and [0122]; Figure 1A). The specification describes the proteins as belonging to the BED-finger domain family, referred to as NRC Interacting Factor –1 (NIF-1) (e.g., paragraph [0051]). The specification states the following with respect to the zinc finger domains, "Although the function of these BED finger domains is not understood, it has been suggested that these proteins may alter local chromatin architecture through association with insulator sequences in the DNA (e.g., paragraph [0122]). The specification teaches that the nucleotide region 5' to the start codon of the protein shown in Figure 1A is not required for

expression of the translated protein, and thus SEQ ID NO: 4 is provided (e.g., paragraph [0053]). SEQ ID NO: 4 is 100% identical to nucleotides 101-4439 of SEQ ID NO: 1. The specification envisions the production of nucleic acid molecules that are 85% similar to the nucleotide sequences of SEQ ID NOS: 1 or 4 (e.g., paragraph [0058]). To determine the percent similarity, the specification envisions using a "basic BLAST" program using the default parameters analysis. The BLAST program is available online at the NCBI web site. Multiple versions of the BLAST program are available, and the default parameters could change over time. Accordingly, reference to BLAST default parameters and a percent similarity does not provide a description of the sequences that are encompassed by the claim. The specification envisions mutations, variations and fragments of the proteins encoded by the nucleic acid molecules of the present invention. Neither the specification nor the claim places any limitation on the number of deletions, additions, or mutations that may be present (e.g., paragraphs [0060]-[0062]). With respect to function, the specification describes NIF-1 as a protein that is capable of interacting with NRC (e.g., Examples 9 and 12). The specification teaches that the LxxLL motif of NRC is not required for interaction with NIF-1 and occurs through a region containing zinc finger 6 or zinc finger 1 (e.g., Examples 14, 15 and 17). No description is provided of any variant of SEQ ID NO: 1 or 4 that encodes a polypeptide that retains the claimed function.

The specification and claims do not indicate what distinguishing structural attributes are shared by the members of the genus. With respect to parts 1 and 2 of claim 1, the specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NOS: 1 and 4. With respect to part 6 of claim 1, the specification and claim do not place any limit on the number of amino acid substitutions,

deletions, insertions and/or additions that may be made to SEQ ID NO: 1 or 4, except that a portion of the nucleic acid sequence must be 85% similar to a portion of SEQ ID NO: 1 or 4. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variable because a significant number of structural differences between the genus members is permitted. The claimed nucleic acid molecule is required only to share a nucleic acid sequence of two nucleotides in common with SEQ ID NO: 1 or 4. The specification does not provide guidance as to what changes should be made. The specification describes the presence of six zinc finger domains, a leucine zipper-like domain and an LxxLL motif. The claim requires the protein encoded by the nucleic acid to modulate transcriptional activation in a cell with or without collaboration with a nuclear hormone receptor transcriptional co-activator. However, the specification does not teach which structures are sufficient for this function. As discussed above, the specification describes zinc fingers 1 and 6 as capable of interacting with NRC. However, the specification does not specifically describe these structures as being capable of modulating transcriptional activation outside of the context of the polypeptide of the full-length NIF-1 polypeptide (e.g., Example 15). The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of the nucleic acid sequence of NIF-1 of SEQ ID NO: 1 or 4 and nucleic acid molecules that encode the polypeptides of SEQ ID NOS: 2 and 3. In the absence of a specific structure/function correlation, one could not predict other structures that necessarily capable of performing the claimed function.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

"A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). In the instant case, the nucleic acid sequences of SEQ ID NOS: 1 and 4 and polypeptide sequences of SEQ ID NOS: 2 and 3, in the absence of a specific structure/function correlation, do not allow one to predict the operability of other nucleic acid molecules such that a representative number of molecules could be envisioned to support the broadly claimed genus.

Given the very large genus of nucleic acid molecules encompassed by the rejected claims, and given the limited description provided by the specification with regard to what

changes that can be made to the proteins of SEQ ID NOS: 2 and 3 while retaining the claimed function, the skilled artisan would not have been able to envision a sufficient number of specific embodiments that meet the functional limitations of the claims to describe the broadly claimed genus. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision a representative number of nucleic acid molecules that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1 and 3-7.

Response to Arguments - - 35 USC § 112

The rejection of claims 2 and 3 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 12/4/2006.

The previous rejection of claims 1-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 12/4/2006. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection presented above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (Molecular and Cellular Biology ,1999, 19(10): 7197-7202, of record in the IDS filed February 2006). The grounds of this rejection have been changed in response to Applicants' amendment of the claims in the response filed on 12/4/2006.

Regarding claim 1, Li et al. teach an isolated human nucleic acid molecule encoding a nuclear receptor coactivator NRIF3 that interacts with hormone receptors in receptor-mediated transcriptional activation (see the Abstract and p. 7193, col. 1, section titled "Cloning of NRIF3). The NRIF3 sequence of Li et al has "a nucleic acid sequence" (i.e., a sequence of at least two nucleotides) in common with SEQ ID NOS: 1 and 4 (e.g., Figure 2). Li et al teach that NRIF3 potentiates TR- and RXR-mediated transactivation *in vivo* (e.g., Abstract; paragraph bridging pages 7194-7195; Figures 5 and 6). Thus, the NRIF3 nucleic acid molecule of Li et al encodes a protein or polypeptide that modulates transcriptional activation in a cell and h as a nucleic acid sequence that has a nucleotide sequence of SEQ ID NO: 1, has a nucleotide sequence of SEQ ID NO: 4, and has a nucleotide sequence (e.g., two nucleotides) with 100% identity to SEQ ID NOS: 1 or 4.

Regarding claims 3 and 4, Li et al teach the NRIF3 nucleic acid ligated into cloning and expression vectors (see especially p. 7192, col. 2, ¶¶2-3), where the expression vector is a circular plasmid containing regulatory regions both 5' and 3' to the inserted NRIF cDNA.

Regarding claims 5-7, Li et al teach HeLa cells transformed with the NRIF3 vector (see p. 7194, Figure 3).

The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989). Thus, Li et al. fully anticipate instant claims 1 and 3-7.

Claims 1 and 3-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al (US Patent 6,783,969; hereinafter Tang). The grounds of this rejection have been changed in response to Applicants' amendment of the claims in the response filed on 12/4/2006.

Regarding claim 1, Tang teaches a human polynucleotide sequence SEQ ID NO: 67 with 96.9% identity to instant SEQ ID NO: 1. Due to the high degree of similarity between the reference and instant sequences, the protein encoded by the reference sequence would necessarily have the function of modulating transcriptional activation (thus meeting the functional limitations of claim 1).

Regarding claims 3 and 4, Tang teaches an expression vector, such as circular plasmids, with regulatory regions 5' and 3' to SEQ ID NO: 67 (e.g., column 15, lines 3-43).

Regarding claims 5-7, Tang teaches host cells transformed with the polynucleotide, including mammalian cells, yeast cells and bacterial cells (e.g., column 20, lines 36-49; column 29, lines. 48-50).

The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989).

Response to Amendment

The declaration filed on 1/16/2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Tang reference.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Tang reference.

The declaration provides evidence that the nucleic acid sequence of SEQ ID NO: 1 and the amino acid sequence of SEQ ID NO: 2 were reduced to practice in this country prior to March 5, 2001. However, the declaration does not show the identical disclosure of the Tang reference, and the claims are drawn to a genus of nucleic acid molecules. The claims are drawn to any isolated nucleic acid molecule that encodes a protein or polypeptide that modulates

transcriptional activation in a cell with or without collaboration with a nuclear hormone receptor transcriptional co-activator and a sequence selected from the group consisting of (i) a nucleic acid molecule having a nucleotide sequence of SEQ ID NO: 1, (ii) a nucleic acid molecule having a nucleotide sequence of SEQ ID NO: 4, (iii) a nucleic acid molecule encoding an amino acid sequence having SEQ ID NO: 3, and (iv) a nucleic acid molecule having a nucleotide sequence that is at least 85% similar to the nucleotide sequence of SEQ ID NOS: 1 or 4 by basic BLAST using default parameters analysis. The recitation of "a nucleotide sequence" reads on any nucleotide sequence of two or more nucleotides. Thus, the claims encompass a broad genus of nucleic acid molecules that share "a sequence" with SEQ ID NO: 1 or 4. The sequence of Tang falls within this genus in that it is 96.9% identical to the sequence of SEQ ID NO: 1. The declaration does not contain facts showing a completion of the invention commensurate in scope with the claims or showing a completion of the same invention that is disclosed by Tang. Applicant has not provided evidence that the differences between SEQ ID NO: 1 and the claimed genus or the sequence of Tang would be obvious to one or ordinary skill in the art prior to the effective date of the Tang reference. See MPEP § 715.02.

Response to Arguments - 35 USC § 102

With respect to the rejection of claims 1 and 3-7 under 35 U.S.C. 102(b) as being anticipated by Li et al, Applicant's arguments filed 12/4/2006 have been fully considered but they are not persuasive.

The response asserts that the fact that NRIF3 contains an LXXLL motif and exhibits a distinct receptor specificity raise the possibility that either the motif and the surrounding amino

acids or another region of the NRIF3 are involved in mediating the receptor-specific interaction of NRIF3. Further, the response asserts that the NIF-1 encoding nucleic acid molecule of the present application is very different from the nucleic acid molecule encoding Li's NRIF3. This is not found persuasive, because the NRIF3 nucleic acid sequence of Li et al meets the structural limitations of the claims in that is has at least two nucleotides (i.e., a sequence) in common with instant SEQ ID NOS: 1 and 4, and is 100% similar over these at least two nucleotides. Further, the nucleic acid molecule meets the functional limitations of the claims in that it encodes a protein that modulates transcriptional activation in a cell. The claims are drawn to a genus of nucleic acid molecules. While instant SEQ ID NOS: 1 and 4 are clearly different than the NRIF3 sequence of Li et al, both sequences meet the structural and functional limitations of the claims. The differences between the instant sequences and the sequences of Li et al do not change the fact that the sequence of Li et al anticipates each of the limitations of the rejected claims.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

With respect to the rejection of claims 1 and 3-7 under 35 U.S.C. 102(e) as being anticipated by Tang et al, Applicant's arguments filed 12/4/2006 have been fully considered but they are not persuasive.

The response asserts that there are differences between SEQ ID NO: 1 and the sequence of Tang (note: the rejection relies upon SEQ ID NO: 67 of Tang). In view of these differences, the response asserts that it is not proper to assume that both sequences carry out the function of encoding a polypeptide that modulates transcriptional activation in a cell. This is not found

persuasive, because the polypeptide encoded by SEQ ID NO: 67 is 99% identical to instant SEQ ID NO: 2 over amino acid residues 132-1357 (see the alignment in Exhibit I). According to Figure 1A of the specification, this portion of the protein contains the six zinc fingers, leucine zipper-like region and LxxLL sequence. Absent any evidence to the contrary, the protein of Tang et al would necessarily be capable of modulating transcription activation in a cell.

The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989). Applicant has not provided evidence that the difference in sequence between SEQ ID NO: 1 of the specification and SEQ ID NO: 67 of Tang results in a polypeptide that does not modulate transcription activation.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER

Blast 2 Sequences results

PubMed Entrez BLAST OMIM Taxonomy Structure

BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.15 [Oct-15-2006]

Matrix BLOSUM62 gap open: 11 gap extension: 1
x_dropoff: 50 expect: 10.000 wordsize: 3 Filter ☐ View option Standard
Masking character option X for protein, n for nucleotide Masking color option Black
☐ Show CDS translation Align

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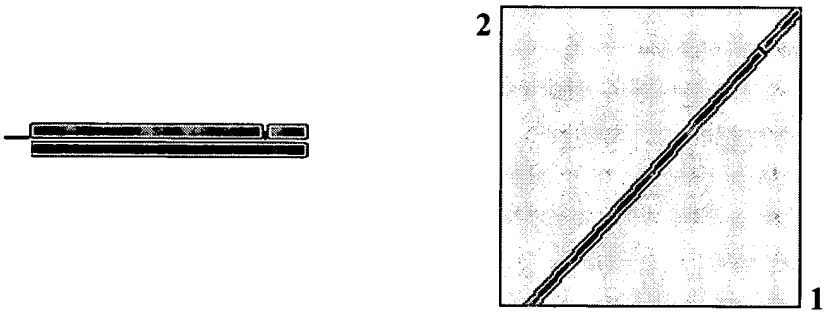
Length = 1357 (1 .. 1357)

Sequence 2: lcl|Tang_SID_67_ORF
Length = 1234 (1 .. 1234)



NOTE:Bitscore and expect value are calculated based on the size of the nr database.

Score = 2497 bits (6471), Expect = 0.0
Identities = 1223/1234 (99%), Positives = 1225/1234 (99%), Gaps = 8/1234 (0%)

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Sbjct  1     MLVSDCTASSSDLGSAIDKIIESTIGPDLIQNCITVTSAEDGGAETTRYLILQGPDDGAP  60

Query  192   MTSPMSSSTLAHSLAAIEALADGPTSTSTCLEAQGGPSSPVQLPPASGAEEPDLQSLEAM  251
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Sbjct  61    MTSPMSSSTLAHSLAAIEALADGPTSTSTCLEAQGGPSSPVQLPPASGAEEPDLQSLEAM  120

Query  252   MEVVVVQQFKCKMCQYRSSTKATLLRHMRERHFRPVAAAAAAAAGKKGRLRKWSTSTKSQE  311
             MEVVVVQQFKCKMCQYRSSTKATLLRHMRERHFRPVAAAAAAAAGKKGRLRKWSTSTK+QE
Sbjct  121   MEVVVVQQFKCKMCQYRSSTKATLLRHMRERHFRPVAAAAAAAAGKKGRLRKWSTSTKTQE  180

Query  312   EEGPEEEDDDDIVDAGAIDDLEEDSDYNPAEDEPRGRQLRLQRPTPSTPRPRRRPGRPRK  371
             EEGPEEEDDDDIVDAGAIDDLEEDSDYNPAEDEPRGRQLRLQRPTPSTPRPRRRPGRPRK
Sbjct  181   EEGPEEEDDDDIVDAGAIDDLEEDSDYNPAEDEPRGRQLRLQRPTPSTPRPRRRPGRPRK  240
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Query  372   LPRLEISDLPDGVEGEPLVSSQSGQSPPEPQDPEAPSSSGPGHLVAMGKVSRTPVEAGVS  431
             LPRLEISDLPDGVEGEPLVSSQSGQSPPEPQDPEAPSSSGPGHLVAMGKVSRTPVEAGVS
Sbjct  241   LPRLEISDLPDGVEGEPLVSSQSGQSPPEPQDPEAPSSSGPGHLVAMGKVSRTPVEAGVS  300

Query  432   QSDAENAAPSCPDEHDTLPRRRGRPSRRFLGKKYRKYYYKSPKPLLRPFLCRICGSRFLS  491
             QSDAENAAPSCPDEHDTLPRRRGRPSRRFLGKKYRKYYYKSPKPLLRPFLCRICGSRFLS
Sbjct  301   QSDAENAAPSCPDEHDTLPRRRGRPSRRFLGKKYRKYYYKSPKPLLRPFLCRICGSRFLS  360

Query  492   HEDLRFHVNSHEAGDPQLFKCLQCSYRSRRWSSLKEHMFNHVGSKPYKCDECSYTSVYRK  551
             HEDLRFHVNSHEAGDPQLFKCLQCSYRSRRWSSLKEHMFNHVGSKPYKCDECSYTSVYRK
Sbjct  361   HEDLRFHVNSHEAGDPQLFKCLQCSYRSRRWSSLKEHMFNHVGSKPYKCDECSYTSVYRK  420

Query  552   DVIRHAAVHSRDRKKRPDPTPKLSSFPCPVCGRVYPMQKRLTQHMKTHSTEKPHMCDKCG  611
             DVIRHAAVHSRDRKKRPDPTPKLSSFPCPVCGRVYPMQKRLTQHMKTHSTEKPHMCDKCG
Sbjct  421   DVIRHAAVHSRDRKKRPDPTPKLSSFPCPVCGRVYPMQKRLTQHMKTHSTEKPHMCDKCG  480

Query  612   KSFKKRYTFKMHLLTHIQAVANRRFKCEFCEFVCEDKKALLNHQLSHVSDKPFKCSFCPY  671
             KSFKKRYTFKMHLLTHIQAVANRRFKCEFCEFVCEDKKALLNHQLSHVSDKPFKCSFCPY
Sbjct  481   KSFKKRYTFKMHLLTHIQAVANRRFKCEFCEFVCEDKKALLNHQLSHVSDKPFKCSFCPY  540

Query  672   RTFREDFLLSHVAVKHTGAKPFACEYCHFSTRHKKNLRLHVRCRHASSFEEWGRRHPEEP  731
             RTFREDFLLSHVAVKHTGAKPFACEYCHFSTRHKKNLRLHVRCRHASSFEEWGRRHPEEP
Sbjct  541   RTFREDFLLSHVAVKHTGAKPFACEYCHFSTRHKKNLRLHVRCRHASSFEEWGRRHPEEP  600

Query  732   PSRRRPFFSLQQIEELKQQHSAAPGPPPSSPGPPEIPPEATTFQSSEAPSLLCSDTLGGA  791
             PSRRRPFFSLQQIEELKQQHSAAPGPPPSSPGPPEIPPEATTFQSSEAPSLLCSDTLG A
Sbjct  601   PSRRRPFFSLQQIEELKQQHSAAPGPPPSSPGPPEIPPEATTFQSSEAPSLLCSDTLGSA  660

Query  792   TIIYQQGAEESTAMATQTALDLLLNMSAQRELGGTALQVAVVKSEDVEAGLASPGGQPSP  851
             TIIYQQGAEESTAMATQTALDLLLNMSAQRELGGTALQVAVVKSEDVEAGLASPGGQPSP
Sbjct  661   TIIYQQGAEESTAMATQTALDLLLNMSAQRELGGTALQVAVVKSEDVEAGLASPGGQPSP  720

Query  852   EGATPQVVTLHVAEPGGGAAAESQLGPPDLPQITLAPGPFGGTGYSVITAPPMEEGTSAP  911
             EGATPQVVTLHVAEPGGGAAAESQLGPPDLPQITLAPGPFGGTGYSVITAPPMEEGTSAP
Sbjct  721   EGATPQVVTLHVAEPGGGAAAESQLGPPDLPQITLAPGPFGGTGYSVITAPPMEEGTSAP  780

Query  912   GTPYSEEPAGEAAQAVVVSDTLKEAGTHYIMATDGTQLHHIELTADGSISFPSPDALASG  971
             GTPYSEEPAGEAAQAVVVSDTLKEAGTHYIMATDGTQLHHIELTADGSISFPSPDALASG
Sbjct  781   GTPYSEEPAGEAAQAVVVSDTLKEAGTHYIMATDGTQLHHIELTADGSISFPSPDALASG  840

Query  972   AKWPLLQCGGLPRDGPEPPSPAKTHCVGDSQSSASSPPATSKALGLAVPPSPPSAATAAS  1031
             AKWPLLQCGGLPRDGPEPPSPAKTHCVGDSQSSASSPPATSKALGLAVPPSPPSAATAAS
Sbjct  841   AKWPLLQCGGLPRDGPEPPSPAKTHCVGDSQSSASSPPATSKALGLAVPPSPPSAATAAS  900

Query  1032  KKFSCKICAEAFPGRAEMESHKRAHAGPGAFKCPDCPFSARQWPEVRAHMAQHSSLRPHQ  1091
             KKFSCKICAEAFPGRAEMESHKRAHAGPGAFKCPDCPFSARQWPEVRAHMAQHSSLRPHQ
Sbjct  901   KKFSCKICAEAFPGRAEMESHKRAHAGPGAFKCPDCPFSARQWPEVRAHMAQHSSLRPHQ  960

Query  1092  CSQCSFASKNKKDLRRHMLTHTKEKPFACHLCGQRFNRNGHLKFHIQRLHSPDGRKSGTP  1151
             CSQCSFASKNKKDLRRHMLTHTKEKPFACHLCGQRFNRNGHLKFHIQRLHSPDGRKSGTP
Sbjct  961   CSQCSFASKNKKDLRRHMLTHTKEKPFACHLCGQRFNRNGHLKFHIQRLHSPDGRKSGTP  1020

Query  1152  TARAPTQTPTQTIILNSDDETLATLHT--------ALQSSHGVLGPERLQQALSQEHIIV  1203
             TARAPTQTPTQTIILNSDDETLATLH+        ALQSSHGVLGPERLQQALSQEHIIV
Sbjct  1021  TARAPTQTPTQTIILNSDDETLATLHSELPLGPQAALQSSHGVLGPERLQQALSQEHIIV  1080

Query  1204  AQEQTVTNQEEAAYIQEITTADGQTVQHLVTSDNQVQYIISQDGVQHLLPQEYVVVPEGH  1263
             AQEQTVTNQEEAAYIQEITTADGQTVQHLVTSDNQVQYIISQDGVQHLLPQEYVVVPEGH
Sbjct  1081  AQEQTVTNQEEAAYIQEITTADGQTVQHLVTSDNQVQYIISQDGVQHLLPQEYVVVPEGH  1140
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Query  1264  HIQVQEGQITHIQYEQGAPFLQESQIQYVPVSPGQQLVTQAQLEAAAHSAVTAVADAAMA  1323
             HIQVQEGQITHIQYEQGAPFLQESQIQYVPVSPGQQLVTQAQLEAAAHSAVTAVADAAMA
Sbjct  1141  HIQVQEGQITHIQYEQGAPFLQESQIQYVPVSPGQQLVTQAQLEAAAHSAVTAVADAAMA  1200

Query  1324  QAQGLFGTDETVPEHIQQLQHQGIEYDVITLADD  1357
             QAQGLFGTDETVPEHIQQLQHQGIEYDVITLADD
Sbjct  1201  QAQGLFGTDETVPEHIQQLQHQGIEYDVITLADD  1234



CPU time:      0.04 user secs.       0.00 sys. secs          0.04 total secs.

Lambda     K      H
   0.313    0.129    0.384

Gapped
Lambda     K      H
   0.267   0.0410    0.140


Matrix: BLOSUM62
Gap Penalties: Existence: 11, Extension: 1
Number of Sequences: 1
Number of Hits to DB: 16,424
Number of extensions: 8970
Number of successful extensions: 85
Number of sequences better than 10.0: 1
Number of HSP's gapped: 2
Number of HSP's successfully gapped: 1
Length of query: 1357
Length of database: 1,634,352,245
Length adjustment: 148
Effective length of query: 1209
Effective length of database: 1,634,352,097
Effective search space: 1975931685273
Effective search space used: 1975931685273
Neighboring words threshold: 9
X1: 16 ( 7.2 bits)
X2: 129 (49.7 bits)
X3: 129 (49.7 bits)
S1: 42 (21.9 bits)
S2: 86 (37.7 bits)
```